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Traversal

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According to MPEP § 803, there are two criteria for a proper requirement for restriction between patentably distinct inventions: (A) The inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i)); and (B) there must be a <u>serious</u> burden on the examiner if restriction is required (emphasis added).

## No Serious Burden

Applicant believes that there is no serious burden on the Examiner with respect to examination of the claim of Group I in addition to the claims of elected Group II, because many of the elements of the dependent claims are substantially similar. Thus, although the independent claims of each of the Groups differ in scope, there is no <u>serious</u> burden on the Examiner with respect to examination of claims 1-33 and 35-68, and the restriction should be withdrawn.

## Process / Apparatus

In the Office Action, the Examiner asserted that the claims of Groups I and II are distinct from each other because Groups I and II are related as process and apparatus. Applicant respectfully requests withdrawal of the requirement for restriction between Groups I and II because the Examiner has not established that an apparatus of Group II as claimed can be used to practice a process that is materially different from that recited in the claims of Group I.

In the Office Action, the Examiner asserted that the apparatus as claimed can be used to practice another materially different process, such as using the apparatus for monitoring and storing heart rate measurements while a patient is both asleep and in an awakened state.

Applicant submits that to the extent the apparatuses of Group II may be used to practice the process proposed by the Examiner, the methods of Group I may also be used to practice the same process. For example, both independent claims 1 (Group I) and 19 (Group II) relate to determining a value of a sleep metric based on physiological parameters of a patient. The method of claim 1 includes "monitoring a plurality of physiological parameters of a patient," while the system of claim 19 includes a plurality of sensors to generate a signal as a function of at least one physiological parameter of a patient. Thus, if the sensors of the system of claim 19 may be used to monitor and store heart rate measurements, it is clear that the method of claim 1, and

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in particular, "monitoring a plurality of physiological parameters of a patient" may also be used to monitor and store heart rate measurements.

The Office Action also indicates that because the method of Group I "consists of using the data to trigger a neurostimulation program upon detection of a sudden change in the heart rate value ...," the claims of Group I are directed toward an invention that is independent and distinct from the invention recited in the claims of Group II. Applicant respectfully points out that the claims of Group I do not recite such a limitation. However, assuming the Examiner is referring to dependent claim 14 (Group I), which recites a method that includes controlling delivery of a therapy based on the determination of whether the patient is asleep, Applicant respectfully submits that claim 14 is a dependent claim, and independent claims 1, 46, and 63 of Group I do not require such a limitation. In addition, Group II, and in particular, dependent claim 43, includes a similar limitation. Accordingly, the inventions of Groups I and II are not independent or distinct.

Based on the foregoing reasons, the restriction between Group I and Group II is improper and should be withdrawn.

By:

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